SH-24

BIOCOM

January 28, 2005

Gary M. Jackson
Assistant Administrator for Size Standards
U.S. Small Business Administration
409 3rd Street S.W.
Washington, D.C. 20416
Via Fax: (202) 205-6930

RE: RIN 3245-AF22- Small Business Size Standards and Issues

Dear Administrator Jackson:

I am writing this letter on behalf of the 400 companies, firms and institutional members within BIOCOM, the trade association representing the life science industry in the Southern California region. I am hereby providing our comments in response to the December 3, 2004 ANPRM on size standards and participation of venture backed companies related to the Small Business Innovation Research program (69 Fed. Reg. 70197).

Issue #1: Size Standards

BIOCOM fully supports the exclusion of affiliates for venture controlled companies (VCC) in size determination for eligibility of the SBIR Program. We believe this is appropriate given that the very nature of venture capital firms is to invest in a variety of companies in order to diversify and reduce risk; therefore a portfolio of companies in which investments are made will almost always result in more than 500 employees. Additionally, we contend that there are operational challenges with regard to a company having the ability to report accurate information about one of its investors without knowledge of their portfolio of client companies.

Issue #2: Should the SBIR Program allow businesses that are majority owned or controlled by venture capitalist companies to remain eligible for grant awards.

The SBA is seeking comment on whether to change current rules regarding majority VC ownership. We believe, based on conversations with our member companies who have participated in the SBIR Program, that this would simply be codifying a common operating procedure of allowing such grants prior to 2003, at which time the SBA apparently changed the definition of "individual" in the eligibility requirements to "natural persons" and excluded venture backed companies.

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Our membership has a great interest in the eligibility requirements as they have been long time participants in the SBIR grant program. Southern California is a magnet for both venture capital and public grant funding. Southern California's emergence as a major life science cluster is in large part due to the strong research base of the region and the contribution of the SBIR grant program. This is a testament that the current system works as the Congress intended.

The majority of our 500+ life science entities are small companies by SBA definition. If the eligibility requirements are codified to exclude majority venture backed companies, most of these companies would no longer qualify for SBIR grants. This would be of detriment to the companies who have factored grants and grant supported research activities into their business model. It would also negatively impact the ability of the awarding agencies to fund the top tier of research that has been validated by the investment of private market sources.

A diverse portfolio of investment that includes a combination of venture capital, angel investors, personal investment, private partnerships, public offerings and grants is critical for small companies to meet all of the financial challenges they face in taking new and innovative products from the laboratory to the market. Additionally, there is a noted synergistic relationship between private and public investment in that many grants require additional investment and venture capitalists view grant awards as a sign of viability. This typical combination of venture funding, industry collaboration and only modest investment directly by individuals, boosts "non-individual" ownership above the 51 percent level very early in a company's existence and, in virtually every instance, would render the small business ineligible for SBIR funding.

We have surveyed our Southern California regional cluster and have found that many, if not most, of our life science firms would fail the "individual" test if venture capital investors, larger corporate collaborations and pension funds were to be excluded from the "51 percent rule" under the SBA's current strict interpretation. The demographics of the Southern California life science cluster are unique in that the industry is relatively immature yet experiencing tremendous growth. While we have a few large life science companies, a recent survey conducted by BIOCOM and Ernst & Young found that only 12% of our companies have more than 250 full time employees and a full quarter of are less than five years old. While only a small number have products on the market, the survey also conveyed the potential for success of Southern California's market, with fifty-two companies having a combined 86 drugs and diagnostics in Phase II and Phase III with another 135 in clinical trials.

As Chairman of the Council of State Biotechnology Associations, my experience in discussing this issue with my counterparts in other regions leads me to conclude that such an exclusion would be a very heavy blow not only to this region, but to a number of other established and newly emerging life science clusters in the United States. We are therefore especially troubled by the negative precedent this determination could set across the country.

The life science industry is critical to the future of America's health care system and the new economy. It is also becoming a key player in the war against bioterrorism, largely through SBIR funding programs within the NIH. After reviewing the ANPRM, BIOCOM believes that the SBA's should allow venture backed companies to participate in the SBIR Program. We urge you to closely review this policy and to make appropriate changes in your policy for interpretation of the SBIR regulations so as to ensure that small life science companies will continue to qualify for SBIR grants.

Thank you for your consideration. I would also like to request in that the Small Business Administration hold one of its field hearings on this issue in San Diego.

Sincerely,

Joseph D. Panetta
President & CEO